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Fax Number 703-305-3014, Attention: R. SCHWADRON Art Unit 1644

Date: June 27, 2002 By: Lois Miller
Lois Miller

PATENT

Attorney Docket No.
DX0612K1B

CN 028008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gorman, et al.

Serial No.: 09/545,998

Filed: April 10, 2000

For: MAMMALIAN CELL SURFACE
ANTIGENS; RELATED
REAGENTS

Examiner: R. Schwadron

Art Unit: 1644

**RESPONSE TO RESTRICTION
REQUIREMENT**

Palo Alto, California 94304

June 26, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is a response to the Restriction Requirement (Species election) dated May 22, 2002 (paper number 10). Accompanying this response is a petition for a one-month extension of time and fee, thereby extending the time to respond from June 22, 2002 to July 22, 2002.

Claims 6, 12, and 23-29 are pending.

The following reiterates Applicants' earlier Response to Restriction Requirement (Species election). The Examiner has further required a species election of the previously restricted and examined group (See paper numbers 3, 4, 5, and 6, for the present application).

1. The Examiner required election between the (a) antibody and (b) antibody fragments of Claim 6.

2. If the species of antibody was selected above, the Examiner further required election between the detectably labeled antibody of Claim 24 and the antibody attached to a solid substrate of Claim 25.

3. The Examiner next required election between the (a) polyclonal antibody and (b) monoclonal antibody of Claim 26.

4. The Examiner further required election between the (a) Fab fragment, (b) Fab' fragment, (c) F(ab)₂ fragment, and (d) Fv fragment of Claim 28, if the antigen binding fragment of Claim 6 was selected.

Applicants provisionally elect, with traverse, the antibody of Claim 6, the detectably labeled antibody of Claim 24, and the monoclonal antibody of Claim 26.

Applicants traverse the present species elections on several grounds.

First, Applicants submit that the requirement to elect either the antibody or antigen binding fragment is not proper. Applicants point out that although these molecules may be structurally different, an antigen binding fragment of an antibody should bind to the same target antigen as the complete antibody and exert the similar effects. Applicants thus respectfully disagree with the Examiner's assertion that the antigen binding fragment and the antibody are functionally distinct.

Furthermore, Applicants submit that it is current Office practice to allow patents containing claims to both antibodies and antibody binding fragments. See, e.g., U.S. Patent Nos. 6,342,221; 6,265,549; 6,143,273; 6,080,407; 6,001,358; 5,709,858; 6,352,832; 6,335,175; 6,329,159; 6,326,482; 6,312,694; 6,294,172.

In view of the above, Applicants do not believe it would be a serious burden on the Examiner to examine the (a) antibody and (b) antigen binding fragment of the present invention together. Since the Examiner has not put forth a reason as to why it would be a serious burden to examine the claims in these two groups together, Applicants believe that MPEP §803 (MPEP, August 2001) compels the examination of these groups together.

Next, Applicants disagree with the Examiners statement that the detectably labeled antibody of Claims 24 and the antibody bound to a solid substrate of Claim 25 have different functional properties. Again both modifications to the base antibody will

still yield an antibody capable of binding to the same target antigen. Both types of modified antibodies can function in the purification of the target antigen. As above Applicants respectfully submit that the Examiner has not shown why examining the antibodies of Claims 24 and 25 together would be a serious burden. Rejoinder is respectfully requested.

Applicants further respectfully disagree with the Examiner's requirement to select either polyclonal or monoclonal antibodies. Again, Applicants point out that the polyclonal and monoclonal antibodies of the present invention will bind the same target antigen. In fact the monoclonal antibodies are a subset of the polyclonal antibodies. The PTO has, in the past, issued patents to both polyclonal and monoclonal antibodies, thus evidencing that the burden of search was not serious.

Finally, Applicants respectfully traverse the Examiner's requirement that if an antigen binding fragment is selected, Applicants would be further subjected to an additional species election of one of the four fragment types listed in Claim 28. Again the Applicants point out that the fragment types listed in Claim 28 all bind the target antigen and are thus not functionally distinct. Again, the PTO has been in the practice of issuing patents to various fragments of antibodies in one patent. Applicants again submit that the Examiner has not put forth reasons as to why examining the fragments of Claim 28 together would be a serious burden.

The following is a list of all unamended claims that read upon the elected species:

6. An antibody or antigen binding fragment thereof which specifically binds a protein or peptide of SEQ ID NO:2 or 4.
12. A kit comprising:
 - a) a substantially pure protein or peptide of SEQ ID NO:2 or 4; and
 - b) an antibody or receptor which specifically binds a protein or peptide of SEQ ID NO:2 or 4.
23. A sterile or buffered composition comprising the antibody of Claim 6.

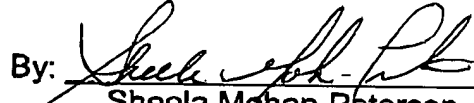
24. The antibody of Claim 6 which is detectably labeled.
25. The antibody of Claim 6 which is attached to a solid substrate.
26. The antibody of Claim 6 which is a:
 - a) polyclonal antibody; or
 - b) monoclonal antibody.
28. The antibody of Claim 6, wherein the antigen binding fragment is a:
 - a) Fab fragment;
 - b) Fab' fragment; or
 - c) F(ab)₂ fragment;
 - d) Fv fragment.
29. The antibody of Claim 6 which is a humanized antibody.

Applicants reserve the right to file subsequent applications claiming the non-elected subject matter and do not waive any of their rights or abandon any non-elected subject matter. Since Applicants have fully and completely responded to the Restriction Requirement and have made the required election, this application is now in order for early action.

Applicants believe that no additional fees are due with this communication. Should this not be the case, the Director is hereby authorized to debit any changes or refund any overpayments to DNAX Deposit Account No. 04-1239. If the Examiner believes that a telephone conference would aid the prosecution of this case in any way, please call the undersigned.

Respectfully submitted,

Date: June 26, 2002

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